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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/914,149 | 12/19/2001 | Fatima Gebauer | 71745-56434 | 1757 |

24232 7590 11/16/2004

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| EXAMINER |
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STRZELECKA, TERESA E

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| ART UNIT | PAPER NUMBER |
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1637

DATE MAILED: 11/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 09/914,149 | GEBAUER ET AL. | |
| | Examiner | Art Unit | |
| | Teresa E Strzelecka | 1637 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 30 August 2004.
 2a) This action is FINAL. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 45,52-54,57-59 and 61-76 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) _____ is/are rejected.
 7) Claim(s) _____ is/are objected to.
 8) Claim(s) 45, 52-54, 57-59, 61-76 are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This office action is in response to an amendment filed August 30, 2004. Claims 45-60 were previously pending. Applicants cancelled claims 46-51, 55, 56 and 60, and added new claims 61-76 (note to Applicants: claim 61 should have an indicator "new", as it was not previously presented). The amended claims 45, 52-54, 57-59 and 61-64 and the newly added claims 65-76 constitute two different inventions, therefore this office action is an Election/Restriction Requirement.

Election/Restrictions

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:
- I. Claims 45, 52-54, 57-59 and 61-64, drawn to a method for producing a protein by *in vitro* translation, the method comprising:
- a) preparing a *Drosophila* embryo cell extract by a method comprising dechorionating *Drosophila* embryos in an aqueous isotonic solution comprising detergent and bleach;
- b) adding an exogenous ribonucleic acid template having both a 5' cap and a 3' poly A tail to a translation mix in the presence of said *Drosophila* embryo cell extract to form a reaction mix; and
- c) incubating said reaction mix with said exogenous ribonucleic acid template having both a 5' cap and a 3' poly A tail under conditions such that translation of said exogenous ribonucleic acid template produces an encoded proteins, classified in class 435, subclass 91.2, for example.
- II. Claims 65-76, drawn to a method for producing a protein by *in vitro* translation, the method comprising:

- a) producing a Hela cell extract by a method that comprises:
 - i) harvesting Hela cells grown in culture,
 - ii) centrifuging said Hela cells,
 - iii) resuspending said Hela cells in a hypotonic buffer,
 - iv) lysing said Hela cells using a homogenizer to create a Hela cell homogenate,
 - v) centrifuging said Hela cell homogenate for five minutes or less, and
 - vi) removing the supernatant of the centrifuged homogenate to obtain a Hela cell extract; and
- b) incubating said Hela cell extract with an exogenous ribonucleic acid template having both a 5' cap and a 3' poly A tail under conditions such that translation of said ribonucleic acid template produces an encoded protein, classified in class 435, subclass 91.2, for example.

The inventions are distinct, each from the other because of the following reasons:

3. Inventions I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are directed to methods with different starting materials and method steps.

The instant specification does not disclose that these methods would be used together. The method of producing a protein by in vitro translation using a Drosophila embryo cell extract (Group I) and the method of producing a protein by in vitro translation using a HeLa cell extract (Group II) are unrelated as they comprise distinct steps and utilize different products which demonstrates that each method has a different mode of operation. Each invention performs this function using a

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structurally and functionally divergent material. In case of Group I, the material used is Drosophila embryo cell extract, whereas in the case of Group II it is HeLa cell extract. Therefore, each method is divergent in materials and steps. For these reasons the Inventions I and II are patentably distinct.

Furthermore, the distinct steps and products require separate and distinct searches. The inventions of Groups I and II have a separate status in the art therefore it would be burdensome to search the inventions of Groups I and II together.

4. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

5. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Teresa E Strzelecka whose telephone number is (571) 272-0789. The examiner can normally be reached on M-F (8:30-5:30).

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Teresa E Strzelecka
Teresa Strzelecka
Examiner
Art Unit 1637

November 1, 2004